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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NEUROGRAFIX, a California corporation; WASHINGTON RESEARCH FOUNDATION, a not-for-profit Washington corporation,

Plaintiffs,

vs.

SIEMENS MEDICAL SOLUTIONS USA, INC., a Delaware corporation; and SIEMENS AKTIENGESELLSCHAFT, a German corporation,

Defendants.

CASE NO. CV 10-1990 MRP(RZX)

SIEMENS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF SIEMENS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY BASED ON INDEFINITENESS OF "CONSPICUITY" IN CLAIMS 1, 3, 7, 11, 12, 18, AND THEIR ASSERTED DEPENDENT CLAIMS IN U.S. PATENT NO. 5,560,360

The Hon. Mariana R. Pfaelzer
United States District Court Judge

Hearing Date: **October 5, 2011**
Time: **11 am**
Location: **Courtroom 12**

SIEMENS MEDICAL SOLUTIONS USA, INC.

Counterclaim Plaintiff,

vs.

NEUROGRAFIX, and WASHINGTON RESEARCH FOUNDATION,

Counterclaim Defendants.

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 56-1, Defendant and Counterclaim Plaintiff Siemens Medical Solutions USA, INC. and Defendant Siemens Aktiengesellschaft (collectively "Siemens") hereby submit this separate Statement of Uncontroverted Facts and Conclusions of Law in Support of Siemens' Motion for Partial Summary Judgment of Invalidity Based on Indefiniteness of "Conspicuity" in Claims 1, 3, 7, 11, 12, 18, and Their Asserted Dependent Claims in U.S. Patent No. 5,560,360. To the extent the following Uncontroverted Facts may be deemed to be Conclusions of Law, they are incorporated by reference in the Conclusions of Law. To the extent that the following Conclusions of Law may be deemed to be Uncontroverted Facts, they are incorporated by reference in the Uncontroverted Facts.

I. STATEMENT OF UNCONTROVERTED FACTS

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
1.	The "conspicuity" limitation in claims 1-35 was a significant basis for distinguishing the prior art.	D.I. 107 [Plaintiffs' Claim Construction Reply Brief] at 3.
2.	The calculation of "conspicuity" proposed by Plaintiffs' involves performing a calculation on a single MR image, not a set of images.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 116:20-25.
3.	The method of calculating "conspicuity" proposed by Plaintiffs does not take into account noise.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 74:12-16; Ex. IND2 [Bryan Opening Report] ¶ 26; Ex. IND3 [Bryan Rebuttal Report] ¶ 18.
4.	There is no industry standard, one way of calculating conspicuity.	Brant-Zawadzki Opening Report ¶ 14; Ex. IND2 [Bryan Opening Report] ¶¶ 15-17, 21, 23; Ex. IND3 [Bryan Rebuttal Report] ¶¶ 14-17 (and references cited therein).
5.	The '360 patent does not prescribe one particular method of selecting a region of interest ("ROI") used for the "conspicuity" calculation in claims 1-35.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 53:2-13; Ex. IND2 [Bryan Opening Report] ¶¶ 17, 35.
6.	The '360 patent does not prescribe how to choose the size of the ROIs to use for the "conspicuity" calculation in claims 1-35.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 56:19-23; Ex. IND2 [Bryan Opening Report] ¶ 39.
7.	The '360 patent does not prescribe how to choose the shape of the ROI to use for the "conspicuity" calculation in claims 1-35.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 56:19-23; Ex. IND2 [Bryan Opening Report] ¶ 39.
8.	The '360 patent does not prescribe one standard way of selecting an ROI to use for the "conspicuity" calculation in claims 1-35.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 108:18-109:10; 127:8-128:3; Ex. IND2 [Bryan Opening Report] ¶¶ 17, 35.

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
9.	There is no industry standard one way of selecting an ROI to use for performing measurements on an MR image.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 126:17-127:7; Ex. IND2 [Bryan Opening Report] ¶¶ 17, 30 (and references cited therein); Ex. IND3 [Bryan Rebuttal Report] ¶ 34.
10.	For purposes of calculating the "conspicuity" in claims 1-35 as proposed by Plaintiffs, different operators could choose to use different methods of selecting the ROIs.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 109:7-10.
11.	Manually selecting an ROI is dependent, at least in part, upon the observer's ability to visually distinguish the boundary between two tissues, *e.g.*, the neural tissue and the non-neural tissue.	Ex.IND2 [Bryan Opening Report] ¶ 36.
12.	The '360 patent does not expressly disclose how to select a representative portion of neural or non-neural tissue for purposes of choosing a neural or non-neural ROI.	Ex. IND2 [Bryan Opening Report] ¶ 44; Ex. IND3 [Bryan Rebuttal Report] ¶ 33.
13.	The size, shape, and position of an ROI can change the mean signal intensity measurements resulting from the selected ROI.	Ex. IND2 [Bryan Opening Report] ¶ 39 (and references cited therein).

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
14.	The method of selecting an ROI has a direct influence on quantitative outcome of the signal intensity measurement for a tissue.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 129:19-130:1; 165:21-166:2; Ex. IND2 [Bryan Opening Report] ¶ 30 (and references cited therein), ¶ 39 (and references cited therein); Ex. IND11 [N.C. Krak et al., *Effects of ROI Definition and Reconstruction Method on Quantitative Outcome and Applicability in a Response Monitoring Trial*, 32 Eur. J. Nuclear Med. & Molecular Imaging 294, 294 (2005)] at 294 ("Conclusion: The method of ROI definition has a direct influence on quantitative outcome."); Ex. IND3 [Bryan Rebuttal Report] ¶¶ 33, 46-47 (and references cited therein).
15.	For smaller peripheral nerves, there could be situations where those of skill in the art cannot see the nerve and therefore cannot measure its conspicuity.	Ex. IND1 [Brant-Zawadzki Dep. Tr. 79:9-18]; Ex. IND3 [Bryan Rebuttal Report] ¶ 37.
16.	Plaintiffs contend that the images in Exhibit A to Dr. Filler's Rebuttal Report were made using the method disclosed by the claims of the '360 patent.	Exhibit IND5 [Filler Rebuttal Report, Exhibit A]; Exhibit IND6 [Filler Rebuttal Report] ¶ 48; D.I. 107 [Plaintiffs' Claim Construction Reply Brief] at 8.
17.	The neural tissue in Figures 2, 3, and 8 of Exhibit A to Dr. Filler's Rebuttal Report do not have the strongest signal intensities in the image.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 214:4-215:16; Ex. IND3 [Bryan Rebuttal Report] ¶¶ 20-25; Ex. IND17 [Bryan Rebuttal Report, Exhibit 2].
18.	The method Dr. Bryan used to select ROIs in Exhibit C of his Opening Expert Report illustrates exactly the methods Dr. Brant-Zawadzki discussed in his Opening Report.	Brant-Zawadzki Rebuttal Report ¶¶ 11, 19.

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
19.	The mean signal intensity of the non-neural background tissue adjacent to a nerve varies depending on the ROI selection.	Ex. IND12 [Bryan Opening Report, Exhibit C].
20.	ROIs #1-5 in Figure 7 of Exhibit C to Dr. Bryan's Opening Expert Report identify nerve tissue.	Ex. IND2 [Bryan Opening Report] ¶ 47; Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 7 & Table 7.
21.	ROIs #1-10 in Figure 8 of Exhibit C to Dr. Bryan's Opening Expert Report identify nerve tissue.	Ex. IND2 [Bryan Opening Report] ¶ 48; Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 8 & Table 8.
22.	ROIs #1-8 in Figure 9 of Exhibit C to Dr. Bryan's Opening Expert Report identify non-neural tissue.	Ex. IND2 [Bryan Opening Report] ¶ 51; Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 9 & Table 9.
23.	ROIs #1-5 in Figure 10 of Exhibit C to Dr. Bryan's Opening Expert Report identify non-neural tissue.	Ex. IND2 [Bryan Opening Report] ¶ 52; Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 10 & Table 10.
24.	In Figure 5 of Exhibit C to Dr. Bryan's Opening Report, ROI #2 is adjacent to ROI #1.	Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 5.
25.	In Figure 5 of Exhibit C to Dr. Bryan's Opening Report, ROI #2 is placed in tissue that is surrounding ROI #1.	Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 5.
26.	In Figure 5 of Exhibit C to Dr. Bryan's Opening Report, ROI #2 identifies non-neural tissue.	Ex. IND12 [Bryan Opening Report, Exhibit C] Figure 5.
27.	In Figure 5 (and accompanying table) of Exhibit A to Dr. Filler's Rebuttal Expert Report , Dr. Filler measured a "conspicuity" of 5.22 of the "plexus" neural tissue as compared to the "lung" non-neural tissue.	Ex. IND5 [Filler Rebuttal Report, Ex. A] at Fig. 5; Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 187:5-14.

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
28.	In Figure 6 (and accompanying table) of Exhibit A to Dr. Filler's Rebuttal Expert Report , Dr. Filler measured a "conspicuity" of 4.56 of the "plexus" neural tissue as compared to the "lung" non-neural tissue.	Ex. IND5 [Filler Rebuttal Report, Ex. A] at Fig. 6; Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 188:5-8.
29.	In Figure 7 (and accompanying table) of Exhibit A to Dr. Filler's Rebuttal Expert Report , Dr. Filler measured a "conspicuity" of 3.80 of the "plexus" neural tissue as compared to the "lung" non-neural tissue.	Ex. IND5 [Filler Rebuttal Report, Ex. A] at Fig. 7; Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 188:9-13.
30.	The images (and accompanying tables) in Figures 5, 6, and 7 of Exhibit A to Dr. Filler's Rebuttal Expert Report were all created using the same underlying DICOM data.	Ex. IND5 [Filler Rebuttal Report, Ex. A].
31.	The "intensity" limitation in claim 19 should be understood the same as the "conspicuity" limitation in the other claims, such that claim 19 effectively requires a "conspicuity of the nerve that is at least 5 times that of the non-neural tissue."	Ex. IND6 [Filler Rebuttal Report] ¶ 13; Brant-Zawadzki Rebuttal Report ¶¶ 2-4.
32.	The same DICOM data used to generate Figures 5, 6, and 7 of Exhibit A to Dr. Filler's Rebuttal Expert Report may or may not satisfy the claim 19 "intensity" limitation, depending on how an observer selected the regions of interest to use in the conspicuity calculation.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 188:21-189:2.
33.	In Figure 7 of Exhibit C to Dr. Bryan's Opening Report, adjacent to ROI #4 is tissue that is brighter than the tissue in ROI #4.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 210:5-18.

	UNCONTROVERTED FACTS	SUPPORTING EVIDENCE
34.	In Figure 7 of Exhibit C to Dr. Bryan's Opening Report, ROI #4 identifies nerve tissue.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 208:14-209:16.
35.	In Figure 7 of Exhibit C to Dr. Bryan's Opening Report, the brighter tissue adjacent to ROI #4 contains some non-neural tissue.	Ex. IND1 [Brant-Zawadzki Dep. Tr.] at 210:5-18.
36.	For the purposes of the "conspicuity" calculation proposed by Plaintiffs, the non-neural background tissue can be tissue other than muscle tissue.	Ex. IND12 [Bryan Opening Report, Exhibit C].
37.	For the purposes of the "conspicuity" calculation proposed by Plaintiffs, the non-neural background tissue adjacent to a nerve can be tissue other than muscle tissue.	Ex. IND12 [Bryan Opening Report, Exhibit C].
38.	For the purposes of the "conspicuity" calculation proposed by Plaintiffs, the non-neural background tissue surrounding a nerve can be tissue other than muscle tissue.	Ex. IND12 [Bryan Opening Report, Exhibit C].

II. CONCLUSIONS OF LAW

	CONCLUSIONS OF LAW	LEGAL SUPPORT
1.	A claim is indefinite where it does not inform a person of ordinary skill in the art of the bounds of the invention such that a person of ordinary skill in the art could avoid infringement.	*Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008); *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

	CONCLUSIONS OF LAW	LEGAL SUPPORT
2.	Claims are indefinite if they do not reasonably apprise those skilled in the relevant art of the patent applicant's intended scope of the invention when read in light of the specification.	*Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008); *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005); *Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).
3.	Indefinite claims are invalid as a matter of law under 35 U.S.C. §112, ¶ 2.	*Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1382 (Fed. Cir. 2009).
4.	A dependent claim incorporates the limitations of the claims from which it depends.	35 U.S.C. §112, ¶ 4.
5.	When the meaning of claims is in doubt, especially when there is close prior art, they are properly declared invalid under 35 U.S.C. § 112 ¶ 2.	*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) ("When the meaning of claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid."); *see Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1253 (Fed. Cir. 2008).
6.	Claims 1-35 are indefinite and therefore invalid under 35 U.S.C. § 112 ¶ 2.	*See* accompanying memorandum of points and authorities.

Respectfully submitted,

DATED: August 24, 2011

By: /s/ Sean M. McEldowney

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2011, a copy of the foregoing SIEMENS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW IN SUPPORT OF SIEMENS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY BASED ON INDEFINITENESS OF "CONSPICUITY" IN CLAIMS 1, 3, 7, 11, 12, 18, AND THEIR ASSERTED DEPENDENT CLAIMS IN U.S. PATENT NO. 5,560,360 was served upon counsel of record for Plaintiffs registered with the Court's CM/ECF system.

/s/Sean M. McEldowney